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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/719,516
Filing Date: November 21, 2003
Appellant(s): TANG ET AL.

Bernard Rosse
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 01/04/2010 appealing from the Office action mailed 07/02/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. **Claims 1-3,6-8,11,15,17-18,20,23-25,28 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (US 2001/0014717 A1) and claims 1-3,6-8,11-15,17-18,20,23-**

25,28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 2001/0014717 A1).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 01/21229 A1	Lee	03-2001
EP 0 970 711 A2	Hossainey et al.	02-2000
US 2004/0181271 A1	DeSimone et al.	9-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4,6-8,11,15,17-18,20-21,23-25,28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (WO 01/21229 A1).

Lee teaches an antimicrobial and anti-inflammatory endovascular stent containing a coating comprised of biodegradable polymers including poly(3-hydroxybutyrate-3-hydroxyvalerate) (3-PHB-Co-3-PHV), polycaprolactone (PCL), polyorthoesters, polyglycolic acids (PGA), poly lactic acids (PLA) and blends and combinations thereof. See abstract, pag 6 lin 24-29, pag 7 lin 26-31and claims. Regarding appellants limitation for the glass transition temperature for first polymer, as disclosed within appellants own specification the Tg of pure PCL is -62^{o}C, thus since Lee teaches the use of PCL the claim limitation is considered met. Furthermore the Tg

of a polymer is just a measurable property of that polymer, since the polymers of Lee are the same as applicants claimed first polymer and polymer additive the limitation is inherently met, because it is inherent that the same compound will have the same properties. Regarding appellants limitation that the polymeric additive has a degree of crystallization greater than that of the first polymer, once again since the first polymers and polymeric additives are the same it is inherent that the properties of those polymers including the degree of crystallization will be the same for the same compound or polymer. Also since the process of making the coating for a stent and the polymers are being used for the same intended purpose, the degree of crystallization will inherently be the same. Appellants have not set forth in their claims or within the specification how and why their claimed polymers would have a degree of crystallization different than those same polymers known in the art or that are commercially available. The burden is shifted to appellants to show how the degree of crystallization and Tg for their claimed polymers and polymeric additives are different than those polymers taught by Lee.

Claims 1-3,6-8,11-18,20,23-25,28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (EP 0 970,711 A2).

Hossainy teaches a process for providing coated stents, the stent coating can be comprised of a PCL and PGA blend. See abstract, [0022], [0025], [0029]-[0031]. The coating could be a top coating applied to delay the release of a pharmaceutical agent or the coating can be used as a matrix for the delivery of a pharmaceutically active material. Regarding the limitations on the degree of crystallization and the Tg of the first polymer and polymeric additive, the remarks above regarding Lee are incorporated

herein, that is since the polymers of Hossainy are the same as appellants claims the examiner assumes the properties of those polymers will inherently be the same. The burden is shifted to appellants to show that the polymers of Hossainy would not have the same claimed properties of applicant's polymers. Regarding claims 12-14 and 29-31 Hossainy teaches that PCL and glycolide could be used in a blend of from about 35:65 to 90:10, within applicants claimed mass ratio.

Claims 1-3,6-8,11,15,17-18,20,23-25,28 and 32-4 are rejected under 35 U.S.C. 102(e) as being anticipated by DeSimone et al. (US 2004/0181271 A1, cited previously).

DeSimone teaches an intraluminal prosthesis (including stents) comprised of an erodible polymeric material and a coating which can be comprised of PCL, PGA, PLA and the like and blends thereof. See [0028],[0035]-[0037],[0043] and claims 1,36,38 and 39. Pharmacological agents could be incorporated within the stent or within the coating, since the coating can cover a stent containing the active this would meet the limitation in claim 16 in which a topcoat layer is disposed over a drug reservoir layer. Regarding the limitations on the degree of crystallization and the Tg of the first polymer and polymeric additive, the remarks above regarding Lee are incorporated herein, that is since the polymers of DeSimone are the same as appellants claims the examiner presumes the properties of those polymers will inherently be the same. The burden is shifted to appellants to show that the polymers of DeSimone would not have the same claimed properties. Regarding the limitations within claims 33-34, DeSimone specifically teaches the use of poly(L-lactide). See [0035] and claims 38-39,73 and 74.

Claims 1-3,6-8,11-15,17-18,20,23-25,28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeSimone et al. (US 2004/0181271 A1).

DeSimone is described in the previous office action filed 04/18/2008. DeSimone while describing polymeric blends is silent on specific blend ratios. However adjusting the amounts of biodegradable polymers used as a coating for a stent is clearly a result effective parameter that one of ordinary skill in the art would adjust through routine optimization. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal blend ratio of polymers within a coating by adjusting the blend ratio and types of polymers to find the desired biodegradability for the coating itself and thereby also adjusting the release rate of any active contained within the coating. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of polymer blend ratio within a coating for a stent would have been obvious at the time of appellant's invention. Furthermore it is noted by the examiner that a ratio of 1:1 is within appellants claimed blend ratios, it would be especially obvious that one of ordinary skill in the art would mix two polymers in a blend in equal amounts of 50:50.

(10) Response to Argument

1. **Response to argument over claims 1-4,6-8,11,15,17-18,20-21,23-25,28 and 32 as being rejected under 35 U.S.C. 102(b) over Lee (WO 01/21229 A1).**
2. **Response to argument over claims 1-3,6-8,11-18,20,23-25,28-32 as being rejected under 35 U.S.C. 102(b) over Hossainy et al. (EP 0 970,711 A2).**

3. **Response to argument over claims 1-3,6-8,11,15,17-18,20,23-25,28 and 32-4 as being rejected under 35 U.S.C. 102(e) over DeSimone et al. (US 2004/0181271 A1).**

4. **Response to argument over 1-3,6-8,11-15,17-18,20,23-25,28-34 as being rejected under 35 U.S.C. 103(a) as being unpatentable over DeSimone et al. (US 2004/0181271 A1).**

Appellants assert that the references cited above cannot anticipate their claimed invention because they do not mention the Tg or the crystallinity of the polymers disclosed within. Further appellants argue that the claims set forth what the specific properties of the various polymers must be and could be discovered by simple experimentation to prepare those polymers and there can be no shifting of the burden to appellants.

As detailed in previous office actions it is the position of the examiner that since the polymers taught in the references above are the same as appellants claimed polymers (PCL,PLA,PHB and PGA) they will inherently have the same properties including Tg and degree of crystallization. Degree of crystallinity and glass transition temperature are properties of a polymer, it is noted that appellants are claiming properties of the polymers claimed. Appellants have not set forth in their claims or within the specification how their polymers would have a different degree of crystallization and Tg than those same polymers known in the art or that are commercially available. The examiner can only search for what is claimed, since the polymers claimed are within the same in scope as what is described in the references above the office must presume

that any property derived from those polymers is also necessarily the same. Appellants have provided no evidence other than argument that the polymers described in the prior art would not have the claimed glass transition temperature and degree of crystallinity. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. See In re Brown, 459 F.2d 531, 59 CCPA 1036, 173 USPQ 685 (1972). In re Best, 562 F.2d 1252, 1255 (CCPA 1977). "[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705,708 (Fed. Cir. 1990). A "prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343 (Fed. Cir. 2005).

Appellants further argue that the references above are hopelessly broad in their disclosures of different polymers and blends thereof and there would be no reason for one of ordinary skill in the art to combine two polymers from such broad disclosures to come up with the claimed invention with all of the requisite properties of the claimed

polymer and polymeric additive. Appellant's arguments are similar to the argument that the references above provide no more than laundry list of polymers due to the breadth of their disclosures.

The examiner respectfully disagrees. First the examiner notes that Lee (WO 01/21229 A1) claims PHB, PCL,PGA and PLA in blends, see claim 26. Similarly DeSimone et al. (US 2004/0181271 A1) also claims polymer blends comprising PHB, PCL, PLA and PGA, see claim 39. Thus those polymers are hardly taken from an enormous disclosure or laundry list within the body of the references; instead they are integral components in the invention claimed. With regards to Hossainey, the reference does teach the use of several classes of polymers, but it clearly recites that aliphatic polyesters can be selected and the polyesters can be blends of the following polymers PLA, PCL, PGA, PHB, polyhydroxyvalerate (PHV) and three additional dioxanone polymers. See page 3 line 57-col 4 lin 3. Thus out of this group of polymers that are taught as blends only 3 out of 8 are not claimed polymers by appellants, hardly a hopelessly broad description of the claimed polymer mixture. While there are numerous groups of polymers taught within Hossainey this does not change the fact that the reference clearly teaches the use of aliphatic polyesters and the polyesters can be blends of the claimed first polymer (PHB,PHV, PCL) and polymeric additive (PLA). Thus from this disclosure within Hossainey on the use of aliphatic polyester blends one of ordinary skill in the art could have readily envisaged applicants claimed invention. Hossainey's disclosure of more than one alternative does not preclude its teaching on

polymer mixtures of PLA, PCL, PGA, PHB, and PHV because such disclosure does not criticize, discredit, or otherwise discourage the mixture claimed by appellants.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/James W Rogers, Ph.D./

Examiner, Art Unit 1618

Conferees:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612